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"Your Regulatory Compliance Expert"

May 23, 2017

Mr. Raju Patel
Senior Manager, Dangerous Goods and Environmental Programs
ABBOTT VASCULAR
26531 Ynez Road
Temecula, California 92591

Subject: **RESULTS OF ANNUAL ETHYLENE OXIDE SOURCE TESTING AND LEAK TESTING PERFORMED AT ABBOTT VASCULAR IN TEMECULA, CALIFORNIA**

Dear Mr. Patel:

Please find attached a presentation of the results of the ethylene oxide source testing and leak testing performed at your facility by ECSi, on Tuesday, May 23, 2017. These test results are to be kept with all records pertaining to SCAQMD-required testing of the EtO gas-sterilization system, and are to be made available upon request by the SCAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

The test results indicate that you continue to operate your EtO sterilization and emission-control system (SCAQMD Permit Numbers F83295 and F83299) in compliance with SCAQMD Rule 1405. I will follow up with you in approximately five months to let you know when your next semi-annual leak test is due, and in approximately eleven months to let you know when your next annual source test/leak test is due.

The annual ethylene oxide emissions reported in Table 2 can be used for your facility's annual SCAQMD emissions report. If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer
ECSi

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TABLE 1
ETHYLENE OXIDE CONTROL EFFICIENCY
OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE (ABATOR #2 - F83299)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 23, 2017

CYCLE PHASE	INJECTION TIME	INLET ETO CONC. (PPM)(1)	OUTLET ETO CONC. (PPM)(2)	ETO CONTROL EFFICIENCY
Exhaust(3)	1341	2130	0.01	99.9995
Exhaust	1344	1130	0.01	99.9991
Exhaust	1347	2210	0.01	99.9995
Exhaust	1350	1680	0.01	99.9994
Exhaust	1353	3040	0.01	99.9997
Exhaust	1356	1610	0.01	99.9994
Exhaust	1359	2690	0.01	99.9996
Exhaust	1402	3050	0.01	99.9997
Exhaust	1405	590	0.01	99.9983
Exhaust	1408	535	0.01	99.9981
Exhaust	1411	7.85	0.01	99.8726
Exhaust	1414	5.15	0.01	99.8058
TIME-WEIGHTED AVERAGE:		**1557**	**0.0100**	**99.9726**
Aeration	1417	521	0.01	99.9981
Aeration	1420	208	0.01	99.9952
Aeration	1423	701	0.01	99.9986
TIME-WEIGHTED AVERAGE:		**476.7**	**0.0100**	**99.9973**
			TIME-WEIGHTED AVERAGE CONTROL EFFICIENCY:	**99.9775**
			SCAQMD REQUIRED CONTROL EFFICIENCY:	**99.0**

Notes:
(1) - PPM = parts per million by volume
(2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
(3) - The exhaust phase started at 13:39, ended at 14:16.
(4) - The aeration phase started at 14:16, the first chamber evacuation was tested.

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TABLE 2
ETHYLENE OXIDE MASS EMISSIONS
FROM A GAS STERILIZATION AND EMISSION CONTROL SYSTEM (F83299/F83295)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 23, 2017

CYCLE PHASE	STACK FLOW(1)	OUTLET ETO MASS FLOW(2)	MINUTES/ CYCLE	CYCLES/ YEAR	ANNUAL ETO MASS EMISSIONS(3)
Exhaust	48.5 DSCFM	0.00000006 lbs/min	46	60	0.0001 lbs/year
Aeration	48.5 DSCFM	0.00000006 lbs/min	8	60	0.00003 lbs/year
		TOTAL ANNUAL ETO MASS EMISSIONS			**0.0001 lbs/year**

Notes:
(1) - DSCFM = Dry Standard Cubic Feet per Minute
(2) - lbs/min = pounds per minute
(3) - lbs/year = pounds per year

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TABLE 3
ETHYLENE OXIDE LEAK TESTING
OF A GAS STERILIZATION SYSTEM (F83295)
OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS
IN TEMECULA, CALIFORNIA
ON MAY 23, 2017

COMPONENT GROUP TESTED	LEAKING COMPONENTS FOUND	CONCENTRATION
Gas Cartridge / Injector	None	<1.0 ppm (1)
Sterilizer Inlet / Inbleed Valve	None	<1.0 ppm
Door Seal	None	<1.0 ppm
Sterilizer Outlet / Chamber Drain	None	<1.0 ppm
Venturi System / Filter	None	<1.0 ppm
Emission Control Device Inlet	None	<1.0 ppm

Notes:
(1) - PPM = parts per million by volume

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Ethylene Oxide Mass Emissions Data and Calculations

Abbott Vascular, Inc. - Temecula, CA - May 23, 2017
Abator #2 (F83299) - Sterilizer #2 (F83295)

DeltaP	SqRtDeltaP	Temp (F)	ppm EtO
	Exhaust Phase		
0.11	0.3317	328	0.01
0.11	0.3317	334	0.01
0.11	0.3317	374	0.01
0.11	0.3317	407	0.01
0.11	0.3317	429	0.01
0.11	0.3317	441	0.01
0.11	0.3317	449	0.01
0.11	0.3317	456	0.01
0.11	0.3317	458	0.01
0.11	0.3317	453	0.01
0.11	0.3317	419	0.01
0.11	0.3317	381	0.01
	Aeration Phase		
0.11	0.3317	361	0.01
0.11	0.3317	351	0.01
0.11	0.3317	347	0.01
Average =			
0.1100	0.3317	399	
		= 859	degR

Average Exhaust Concentration = **0.0100**

Average Aeration Concentration = **0.0100**

stack ID =	3	in.
stack area =	0.049	sq. in.
press =	28.75	in. Hg
Tstd =	528	deg R
Pstd =	29.92	in Hg
Cp =	0.99	
Kp =	85.49	
Velocity =	28.74	ft/sec
Flow =	**48.5**	**dscfm**
MWeto =	44.05	
MolVol =	385.32	
ppmv/ft3 =	1000000	
EtO Mass Flow (Exh) =	**0.00000006**	**lbs/min**
min/cycle =	37	
cycles/year =	60	
EtO Emissions (Exh) =	**0.0001**	**lbs/year**
EtO Mass Flow (Aer) =	**0.00000006**	**lbs/min**
min/cycle =	8	
cycles/year =	60	
EtO Emissions (Aer) =	**0.00003**	**lbs/year**
Total EtO Emissions =	**0.0001**	**lbs/year**